



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

09/410,462

10/01/1999

ANGELICA WILLIAMS

ONYX1046-ORD

6889

37499 7590 04/07/2009  
ONYX PHARMACEUTICALS, INC.  
2100 POWELL STREET  
12TH FLOOR  
EMERYVILLE, CA 94608

EXAMINER

ANGELL, JON E

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

04/07/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/410,462	<b>Applicant(s)</b> WILLIAMS ET AL.	
	<b>Examiner</b> J. E. Angell	<b>Art Unit</b> 1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 December 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-11, 15, 17-20, 28 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28 is/are allowed.
- 6) ☒ Claim(s) 6, 7, 11, 15, 17 and 18 is/are rejected.
- 7) ☒ Claim(s) 8-10, 19, 20 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This Action is in response to the communication filed on 12/16/2008.

The amendment filed 12/16/2008 is acknowledged and has been entered.

Claims 6-11, 15, 17-20, 28, 34 are currently pending in the application and are addressed herein.

1. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6, 7, 11, 15, 17, 18 are rejected under 35 U.S.C. 102(e) as being anticipated by anticipated by U.S. Patent No. 6,080,578 (Bischoff et al., previously of record), for the reasons of record.

### ***Response to Arguments***

2. Applicant's arguments filed 12/16/2008 have been fully considered but they are not persuasive.

Art Unit: 1635

3. Applicants submit that the Bischoff et al., does not anticipate the claimed invention for reasons of record as previously discussed by applicants, specifically: (1) Bischoff et al, does not teach all of the elements of the present invention, and (2) the Examiner has failed to establish *a prima facie* case of inherency as the reference of Bischoff, et al, does not inherently teach all of the elements of the present invention.

4. The Office disagrees as previously indicated. Specifically, the claimed method comprises steps that are identical to those of a method taught by Bischoff et al.; therefore, the same result would have necessarily been achieved in the prior art method. Bischoff et al. teaches a cytopathic adenoviral vector comprising a mutation in an E1A CR2 RB family member binding region, as well as methods of using the vector for treatment of tumors by directly administering the vector to the tumor. Therefore, Bischoff et al teaches administering a vector which meets all of the structural limitations of the claims directly to a tumor. In other words, Bischoff et al. teaches administering, directly to a tumor, the exact same vector that is used in independent claims 11, 12 and 15. Since the vector used in the process taught by Bischoff et al. meets all of the structural limitations of the vector used in the method of the instant claims, it would, absent evidence to the contrary, necessarily have all of the same functions. Furthermore, administration of the vector to a subject comprising a tumor, as is taught by Bischoff et al., constitutes administering the vector to a population of cells having dividing endothelial cells and quiescent endothelial cells as subjects harboring tumors have dividing and quiescent endothelial cells. Therefore, administering the vector taught by Bischoff et al directly to a tumor would, in the absence of evidence to the contrary, necessarily result in selective killing of dividing endothelial cells relative to killing of quiescent endothelial cells that are present in the subject.

Art Unit: 1635

5. Applicants argue that inherency is not present when prior art is only capable of being modified.

6. In response, it is pointed out that no modification to the method steps taught by Bischoff et al. is required because all of the active methods steps required by the instant claims is taught by Bischoff et al. The only difference is that Bischoff et al. does not teach that the method results in selective killing of dividing endothelial cells relative to killing of quiescent endothelial cells. Therefore, Applicants have only identified an unknown property which is inherently present in the method taught by Bischoff et al.

7. Therefore, Applicants arguments are not persuasive.

#### ***Allowable Subject Matter***

8. Claim 28 is allowed.

9. Claims 8-10, 19, 20, 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 1635

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. E. Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 7:00 a.m.-5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/  
Primary Examiner, Art Unit 1635

Application/Control Number: 09/410,462

Page 6

Art Unit: 1635